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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/28/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,112	BARTHOLOMAUS ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 9/13/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The translation for many of the foreign patent documents were not provided, therefore they were not considered. It has been placed in the application file, but the information referred to therein has not been considered. Also, the foreign patent document EP0980894 is listed twice in the IDS with two different filing dates

2. The amendment to the claims, filed 11/27/06, is acknowledged. The instant claims 1-8 and 10-40 are pending in the application. Claims 1-8 and 10-28 are currently amended, claim 29 is previously presented, claim 9 was cancelled and claims 30-40 are newly added.

Response to Arguments

3. Applicant's arguments, see response, filed 11/27/06, with respect to ***Claim Rejections - 35 USC § 112*** have been fully considered and are persuasive. The rejection of claim 17 has been withdrawn.

New Rejection

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitation of "a necessary minimum quantity" is confusing. It is unclear as to how much of an aqueous liquid would be considered "a necessary minimum quantity". This rejection was necessitated by the amendment to the claims mailed on 11/27/06.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-8,10,11,17,18,21,23-30,32,36 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Alaux et al. (WO/2000/033835) as stated in the office action mailed on 7/25/06.

8. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive and new rejections are necessitated by the amendment to the claims, which includes newly added claims 30-40.

9. Applicant asserts that Alaux et al. (WO/2000/033835) discloses the concept of avoiding abuse based on visual changes which appear when the dosage form is used improperly and that a dosage form having a breaking strength of at least 500N is not disclosed.

Alaux et al. (WO/2000/033835) teaches of a controlled release dosage form (tablet) including zolpidem, an active ingredient with abuse potential, at least one viscosity increasing microcrystalline cellulose, polymethacrylate polymer that encompasses the polymers of the instant claims, at least one dye (aversive agent) and carnuba wax. The viscosity increasing agent of the disclosure is capable of forming a gel (visual changes) with the assistance of an aqueous liquid which encompasses the viscosity increasing agents of the instant claims as the dosage form of the instant claims also forms a gel (visual changes) upon addition of an aqueous liquid. Therefore, it is erroneous for applicant to argue that the visual changes of the Alaux et al. dosage form would provide for a difference between the dosage forms. The tablet/pellet is prepared from spherical granules as melts upon exposure to heat. These abuse proof dosage tablets of the disclosure encompass the abuse proof dosage tablets of the instant claims and therefore would exhibit a breaking strength equivalent to that of those of the instant claims, 500N.

Claims 1-8,10,11,17,18,21,23-30,32,36 and 40 are directed to an abuse proof dosage form. Since the teachings of Alaux et al. (WO/2000/033835) anticipates the claimed composition, the property of such a claimed composition will also be anticipated by the prior art teaching, since the properties, namely the breaking strength of 500N, are inseparable from its composition. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

It is respectfully pointed out that instant claims 3,11,29,30 and 32 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

10. Claims 1-6,10,11,17,18, 21, 23-27,30-32 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuczynski et al. (US 5,866,164) as stated in the office action mailed on 7/25/06.

11. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive and new rejections are necessitated by the amendment to the claims, which includes newly added claims 30-40.

12. Applicant asserts that Kuczynski et al. (US 5,866,164) discloses an opioid/opioid antagonist composition with a semi-permeable membrane and that the presence of the opioid antagonist neutralizes the pharmaceutical efficacy of the opioid when the form is used improperly. Also, applicant asserts that the dosage form of Kuczynski et al. does not having a breaking strength of at least 500N.

13. Kuczynski et al. (US 5,866,164) teaches an opioid/opioid antagonist tablet containing the polyethylene oxide polymer, which encompasses those polymers/molecular weights of the instant claims. The abuse proof dosage tablets of the disclosure encompass the abuse proof dosage tablets of the instant claims and thus would exhibit a breaking strength equivalent to that of those of the instant claims, 500N. Therefore, it is erroneous for applicant to argue that the semi-permeable membrane of the Alaux et al. dosage form would provide for a difference between the dosage forms since the polymer material is identical. The semi-permeable membrane does not alter the strength characteristics of the polymeric form of the tablet.

Claims 1-6,10,11,17,18, 21, 23-27,30-32 and 40 are directed to an abuse proof dosage form. Since the teachings of Kuczynski et al. (US 5,866,164) anticipates the claimed composition, the property of such a claimed composition will also be anticipated by the prior art teaching, since the properties, namely the breaking strength of 500N, are inseparable from its composition. Therefore, if the prior art teaches the

composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

It is respectfully pointed out that instant claims 3,11,30 and 32 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

14. Claims 1-8,10-18 and 21-34,36,39 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Oshlack et al. (US 2003/0064099A1).

15. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive and new rejections are necessitated by the amendment to the claims, which includes newly added claims 30-40.

16. Applicant asserts that Oshlack et al. (US 2003/0064099A1) that the tampered sustained release dosage form may be manipulated by mechanical, thermal, and/or chemical means (i.e. crushing, shearing, grinding, etc.) and that the dosage form does not have a breaking strength of at least 500N.

17. Oshlack et al. (US 2003/0064099A1) teaches of an abuse proof dosage form of an opioid analgesic with reduced abuse potential due to the addition of an aversive agent, such as a bittering agent that provides burning or irritating effects. The polymers, waxes, irritants, bittering agents, etc. of the disclosure encompass those of the instant claims. The controlled release tablets of the disclosure are prepared in the exact same manner, melt of the multiparticle formulations, as those of the instant claims. The abuse proof dosage tablets of the disclosure encompass the abuse proof dosage tablets of the instant claims and thus would exhibit a breaking strength equivalent to that of those of the instant claims, 500N. The method of mechanical manipulation of the disclosed dosage form may be with any machine that would be able to cut, crush or grind a strong material with a breaking strength of 500N or higher, such as metal or concrete. It is erroneous for applicant to assume that the crushing, grinding of the dosage form of the disclosure would necessarily be the force of a human hand. Therefore the dosage forms of the disclosure would be capable of having a breaking strength of 500N and would encompass the dosage forms of the instant claims.

Claims 1-8,10-18 and 21-34,36,39 and 40 are directed to an abuse proof dosage form. Since the teachings of Oshlack et al. (US 2003/0064099A1) anticipates the claimed composition, the property of such a claimed composition will also be anticipated by the prior art teaching, since the properties, namely the breaking strength of 500N, are inseparable from its composition. Therefore, if the prior art teaches the composition, then the properties are also taught by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is

shifted to Applicant to show that the prior art product does not possess the same properties as the instantly claimed product.

It is respectfully pointed out that instant claims 3,11,29,30 and 32 are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 1-8 and 10-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/2000/033835) in view of the combined disclosures of Oshlack et al. (US 2003/0064099A1), Porter (US 4,175,119) as stated in the office action mailed on 7/25/06. The Miller et al. (US 5,849,240) reference has been removed as it is cumulative.

20. Applicant's arguments filed 11/27/06 have been fully considered but they are not persuasive and new rejections are necessitated by the amendment to the claims, which includes newly added claims 30-40.

21. Applicant's assertions for Alaux et al. (WO/2000/033835) and Oshlack et al. (US 2003/0064099A1) and examiner's reasoning are disclosed above.

22. Applicant asserts that Porter's (US 4,175,119) composition includes an emetic to preclude death from accidental or intentional overdose and that the presence of the emetic chemical causes vomiting when the dosage form is consumed in excessive amounts.

23. The Porter (US 4,175,119) reference was used to show that the emetic, such as emetine (major alkaloid of ipecac syrup) could be a useful agent for the deterrence of abusing/incorrectly consuming a composition that has abuse potential. It would be obvious to substitute the emetic for a bittering agent, hot agent, etc. and/or a neuroleptic drug, such as fluphenazine for an opioid into the dosage forms of Alaux et al. (WO/2000/033835) and/or Oshlack et al. (US 2003/0064099A1) to obtain the most effective abuse proof dosage form.

New Rejection

24. Claims 1-8,10-18,21-36,39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alaux et al. (WO/2000/033835) in view of Oshlack et al. (US 2003/0064099A1) and Sackler (US 2004/0170567).

25. Alaux et al. (WO/2000/033835) discloses a controlled-release abuse proof dosage form of zolpidem or salt thereof. The first phase or immediate phase induces the immediate sleep and is from 0-30 min while the second phase or prolonged release is between 2-6 hours (p1, last paragraph; p2, paragraph 2 and 8). The pellet or tablet prepared from spherical granules or pellets may be incorporated into a multilayer tablet with multiple coatings with an inner layer not containing active substance, thus modulating the release profile (p3, paragraph 2 and 11; p4, paragraph 9). A pellet may be formed from spherical granules as melts upon exposure to heat. The matrix forming excipients include carnauba wax, polymethacrylate, viscosity increasing substance, such as microcrystalline cellulose, (p4, paragraph 2, 7 and 9; p6, paragraph 4 and 18). The formulation may contain calcium carbonate, citric acid as well as other acceptable excipients while the coating may consist of a diffusion limiting polymer, such as ethyl cellulose (p6, paragraph 10 and 11; p4, paragraph 4). Among suitable coloring excipients for preventing abuse are indigotine, yellow orange S, etc. (p7, paragraph 3).

26. Oshlack et al. (US 2003/0064099A1) discloses oral dosage form of an opioid analgesic with reduced abuse potential due to the addition of an aversive agent, such as a bittering agent that provides burning or irritating effects (p1, column 2+). A gelling agent, such as microcrystalline cellulose or polyethylene oxide can also be used to reduce the absorption of the opioid analgesic through injection when the dosage form is tampered with (p2, [0021-0023]; p4, [0049]). Polyalkylene oxide polymer molecular weights vary from 1,000,000 to 10,000,000 (p13, [0151]). The dosage form may be a sustained release form in a matrix with the aversive agents including peppermint oil, oil

of bitter almonds, capsaicin, lemon flavoring, as well as those listed in the instant claims, (p2, [0031]; p3, [0044-0047]; p7, [0080]; claim 4). Suitable controlled release tablets may be formulated from multiparticulate formulations, wet granulation that is compressed into a tablet or melt and may contain hydrophobic binders, such as carnauba wax (p7, [0081]; p8, [0099]; p9, [0110-0111]; p10, [0120]).

27. Sackler (US 2004/0170567) discloses the abuse proof dosage form containing a medicament, such as an opiate, an inactivating agent, such as a dye, etc., irritating agents, such as mustard oil (p1, [0007] and [0014]; p2, [0023] and [0027]). The sustained release tablets may contain a carrier, such as carboxymethyl cellulose, waxes, etc. (p3, [0029] and [0031]).

28. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the mustard oil irritating agent of Sackler (US 2004/0170567) in the abuse proof dosage forms of Alaux et al. (WO/2000/033835) and/or Oshlack et al. (US 2003/0064099A1) to provide for a more effective abuse proof dosage form. Mustard oil extracts are non-toxic, non-carcinogenic and safer to handle than capsaicin (hot substance). Capsaicin is a compound that can be difficult to handle and requires multiple precautions since the oil can be spread from hands, to eyes, etc. and cause a burning sensation to those preparing the dosage form.

Double Patenting

29. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30. Claims 1-8 and 10-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-27 and 36 of copending Application No. 10/567,594. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, opioid antagonists, polymer, wax, irritants (hot substances), dyes, emetic, bitter substance, etc. of the copending application 10/567,594 encompass those of the instant claims. The tablets of the instant claims and copending application 10/567,594 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The tablets of copending application 10/567,594 are thermoformed by extrusion without discoloration which is encompasses

by the thermoformed dosage of the instant claims which does not exclude extruded forms without discoloration.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

31. Claims 1-8 and 10-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 11/349,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, opioid antagonists, polymer, wax, irritants (hot substances), dyes, emetic, bitter substance, etc. of the copending application 11/349,537 encompass those of the instant claims. The tablets of the instant claims and copending application 11/349,537 are in the form of controlled release tablet which are prepared in the same manner (i.e. melt). The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The instant claims may be formed with or without extrusion and therefore encompasses those of copending application 11/349,537 which are thermoformed without extrusion. The instant claims do not exclude preparation of the thermoformed dosage without extrusion.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

32. Claims 1-8,10,27-31 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5,7-9,17 and 18 of copending Application No. 10/890,704. Although the conflicting claims are not identical, they are not patentably distinct from each other because the active ingredient, such as opioid drug, polymer and wax of the abuse-proofed dosage form of the copending application 10/890,704 encompass those of the instant claims. The tablets of the instant claims and copending application 10/890,704 are prepared in the same manner (i.e. melt) and the polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The abuse-proofed dosage form of the copending application 10/890,704 encompasses that of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

33. Claims 1-3,10-20,22-27,30,32-38 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16,18-26,31,36,37 and 38 of copending Application No. 11/113,118. Although the conflicting claims are not identical, they are not patentably distinct from each other because the ingredients, excipients, etc. of the abuse-proofed dosage form, such as opioid drug, opioid antagonists, tranquilizers, irritants (hot substances), emetic, bitter substance, viscosity increasing agent, etc. of the copending application 11/113,118 encompass those of the instant claims. The delayed release tablets of copending

application 11/113,118 encompass the controlled release tablets of the instant claims. The copending application 11/113,118 does not explicitly describe the polymers of the instant claims, it does describe the use of barriers and semi-permeable coatings that cover the layers or core of the dosage form. It is obvious to one skilled in the art to use polymer (materials) for these types of membranes/coatings.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

34. Claims 1-7,10,11,30,31 and 36 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5,7,9-11,19 and 20 of copending Application No. 10/890,703 in view of WO2004/026262. The process for the production of an abuse-proof dosage form of copending application 10/890,703 generates an abuse-proof dosage form where the ingredients, auxiliary substances, etc., such as opioid drug, polymer, etc. 10/890,703 encompass those of the instant claims. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The abuse-proof dosage form of copending application 10/890,703 involves exposing the formulation of an active ingredient and the binder with ultrasound and force. WO2004/026262 discloses preparing a sustained release pharmaceutical composition having a reduced potential for abuse. The application of force, such as ultrasound, pressure, etc. to a composition of an active substance and a water insoluble material generates the abuse-proof dosage form (claims 12-16). At the time of the

invention it would have been obvious to generate the abuse-proof opiate and polymer composition of the instant claims with the method of preparation of WO2004/026262. The resulting abuse-proof dosage form encompasses that of copending application 10/890,703. The application of the mechanical stress (force) results in an insubstantial increase in the immediate aqueous dissolution of the active agent in the composition whereas the dissolution rates are not substantially modifies after the first hour, thus a more effective abuse-proof dosage form.

This is a provisional obviousness-type double patenting rejection.

35. Claims 1-8,11,17,20-32,36 and 38-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/890,707 in view of WO2004/026262. The process for the production of an abuse-proof dosage form of copending application 10/890,707 generates an abuse-proof dosage form that encompasses the abuse-proof dosage form of the instant claims. The ingredients, excipients, etc., such as opioid drug, irritants (hot substances), polymer, emetic, bitter substance, viscosity increasing agent, etc. of the copending application 10/890,707 encompasses that of the instant claims. For instance the (1R,2R)-3-(3-dimethylamino-1-ethyl-2-methyl-propyl)phenol agent of the copending application 10/890,707 anticipates the opiate of the instant claims and the controlled release tablets of the instant claims encompass the delayed release tablets of copending application 10/890,707. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same

breaking strength. The abuse-proof dosage form of copending application 10/890,707 involves exposing the formulation of an active ingredient and the binder with force. WO2004/026262 discloses preparing a sustained release pharmaceutical composition having a reduced potential for abuse. The application of force, pressure to a composition of an active substance and a water insoluble material generates the abuse-proof dosage form (claims 12-16). At the time of the invention it would have been obvious to generate the abuse-proof opiate and polymer composition of the instant claims with the method of preparation of WO2004/026262. The resulting abuse-proof dosage form encompasses that of copending application 10/890,707. The application of the mechanical stress (force) results in an insubstantial increase in the immediate aqueous dissolution of the active agent in the composition whereas the dissolution rates are not substantially modifies after the first hour, thus a more effective abuse-proof dosage form.

This is a provisional obviousness-type double patenting rejection.

36. Claims 1-8,10-13,17,18,20-32,36,38-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 10/890,763 in view of WO2004/026262. The abuse-proof dosage form of copending application 10/890,707 encompasses that of the instant claims whereas the ingredients, excipients, etc., such as opioid drug, irritants (hot substances), polymer, emetic, bitter substance, viscosity increasing agent, etc. are equivalent. For instance the (1R,2R)-3-(2-dimethylaminomenthyl-cyclohexyl)phenol

agent of the copending application 10/890,763 anticipates the opiate of the instant claims and the controlled release tablets of the instant claims encompass the delayed release tablets of copending application 10/890,763. The polymer characteristics of both tablet formulations, such as molecular weight are identical, therefore allowing for the same breaking strength. The abuse-proof dosage form of copending application 10/890,763 involves exposing the formulation of an active ingredient and the binder with force. WO2004/026262 discloses preparing a sustained release pharmaceutical composition having a reduced potential for abuse. The application of force, pressure to a composition of an active substance and a water insoluble material generates the abuse-proof dosage form (claims 12-16). At the time of the invention it would have been obvious to generate the abuse-proof opiate and polymer composition of the instant claims with the method of preparation of WO2004/026262. The resulting abuse-proof dosage form encompasses that of copending application 10/890,763. The application of the mechanical stress (force) results in an insubstantial increase in the immediate aqueous dissolution of the active agent in the composition whereas the dissolution rates are not substantially modifies after the first hour, thus a more effective abuse-proof dosage form.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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MP
December 22, 2006

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SUPERVISORY PATENT EXAMINER